



# 2022 REAL WORLD TESTING RESULTS REPORT

## BlueButtonPRO

### For Criteria

### §170.315 (g)(7) and §170.315 (g)(10)

#### BACKGROUND & INSTRUCTIONS

Under the ONC Health IT Certification Program (Certification Program), health IT developers are required to conduct Real World Testing of their certified health IT (45 CFR 170.405). The Office of the National Coordinator for Health Information Technology (ONC) issues Real World Testing resources to clarify health IT developers' responsibilities for conducting Real World Testing, to identify topics and specific elements of Real World Testing that ONC considers a priority, and to assist health IT developers in developing their Real World Testing plans and results reports.

**While every effort has been made to ensure the accuracy of restatements of 45 CFR Part 170, this template is not a legal document. The official program requirements are contained in the relevant laws and regulations. This resource should be read and understood in conjunction with the following companion resources, which describe in detail many of the Certification Program requirements referenced in this resource.**

- [Real World Testing—What It Means for Health IT Developers – Fact Sheet](#)
- [Real World Testing Resource Guide](#)
- [Real World Testing Certification Companion Guide](#)

Health IT developers should also review the following regulatory materials, which establish the core requirements and responsibilities for Real World Testing under the Certification Program.

- 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule, [85 FR 25642](#) (May 1, 2020) (**ONC Cures Act Final Rule**)
  - [Section VII.B.5](#) — “Real World Testing”

## TEMPLATE INSTRUCTIONS

The following template is organized by elements required to be submitted in the Real World Testing results report. Each section provides a field for submitting responses and/or explanations for how the health IT developer addressed each required element in their Real World Testing approach. These fields serve as a foundation of information required for developing a Real World Testing results report and can be expanded with additional rows or columns to address the specific needs of the Real World Testing results being submitted.

## GENERAL INFORMATION

Plan Report ID Number: Real-World Test Plan Report\_BlueButtonPRO\_2022

Developer Name: Darena Solutions LLC

Product Name(s): BlueButtonPRO

Version Number(s): 2

Certified Health IT Product List (CHPL) Product Number(s): 15.04.04.1322.Blue.02.00.0.200807

Developer Real World Testing Plan Page URL: <https://www.darenasolutions.com/bluebuttonpro-2015-certified-module-cures-update?rq=Costs>

Developer Real World Testing Results Report Page URL [if different from above]:

## [OPTIONAL] CHANGES TO ORIGINAL PLAN

*If a developer has made any changes to their approach for Real World Testing that differs from what was outlined in their plan, note these changes here.*

<b>Summary of Change</b> [Summarize each element that changed between the plan and actual execution of Real World Testing]	<b>Reason</b> [Describe the reason this change occurred]	<b>Impact</b> [Describe what impact this change had on the execution of your Real World Testing activities]
N/A	N/A	N/A

**[OPTIONAL] WITHDRAWN PRODUCTS**

*If a developer withdrew any products within the past year that were previously included in their Real World Testing plan, please provide the following information.*

<b>Product Name(s):</b>	N/A
<b>Version Number(s):</b>	N/A
<b>CHPL Product Number(s):</b>	N/A
<b>Date(s) Withdrawn:</b>	N/A
<b>Inclusion of Data in Results Report:</b> [Provide a statement as to whether any data was captured on the withdrawn products. If so, this data should be identified in the results report.]	N/A

**SUMMARY OF TESTING METHODS AND KEY FINDINGS**

The results of the Real World Testing verify that the BlueButtonPRO certified module does perform as designed in the production environment. The observations documented the interoperability and data exchange as defined in the original test plan. We focused on documenting the number of instances that the certified criteria of the BlueButtonPRO application was successfully used in the real world. To demonstrate the real-world interoperability, we tied our observations to actual efforts that were completed as a part of our clients deploying the application to satisfy the Certify and Provide Information Blocking compliance. We capitalized on the built-in automated testing metrics that collects end-user data from real patients in the live production environment. The BlueButtonPRO application acquires end user data through a FHIR-based API interface and focuses on the patient’s desired EHI. [EHI](#) is the combination of C-CDAs with the USCDv1 data elements, as well as the ability to incorporate any additional document format that contains information used for the care and or treatment of a patient. This process is used to provide easy access to a patient, or their authorized representative, with the ability for them to get the encounter documentation upon the request. The EHR facilitates the invite for the patient/representative to have secure access to obtain the relevant information through a 3<sup>rd</sup>-party application of their choice (e.g., Apple Health). The validation is also preformed that is consistent with the Information Blocking requirements to validate the 3<sup>rd</sup>-party app and authenticate the patient/representative. This workflow provides results for collecting data and successful interoperability workflows between providers and their real patients. We followed our test plan and demonstrated successful real-world implementations with a single and continuous Real World Test Plan and were able to gain confidence that it works in multiple care settings and specialties. We observed that the providers/providers’ staff were able to perform the tasks without assistance from Darena staff, as intended by design. By observing the practices unassisted use of the BlueButtonPRO application as a part of the actual Information Sharing, demonstrated user acceptance and ease of use.

## STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI))

*Both required and voluntary standards updates must be addressed in the Real World Testing plan. Real World Testing plans must include all certified health IT updated to newer versions of standards prior to August 31 of the year in which the updates were made.*

*Indicate as to whether optional standards, via SVAP and/or USCDI, are leveraged as part of the certification of your health IT product(s).*

Yes, I have products certified with voluntary SVAP or USCDI standards. (If yes, please complete the table below.

No, none of my products include these voluntary standards.

<b>Standard (and version)</b>	N/A
<b>Updated certification criteria and associated product</b>	N/A
<b>CHPL Product Number</b>	N/A
<b>Conformance measure</b>	N/A

### Care Setting(s)

*The expectation is that a developer's Real World Testing is conducted within each type of clinical setting in which their certified health IT is marketed. Health IT developers are not required to test their certified health IT in every setting in which it is marketed for use.*

*List each care setting that was tested.*

This plan tested within ambulatory settings with practices up to 150 providers. The plan also included testing within practices of different specialties to confirm that the type of specialty does not play a role in the data requests and or response. The participants were recruited from our extensive base of providers/practices that are signed up have a production interface in place with our BlueButtonPRO application.

### Metrics and Outcomes

This section will detail a summary of the results collected from the BlueButtonPRO application Real World Testing measures as defined in the BlueButtonPRO 2022 Real World Test plan. The outcomes are captured when the users with a BlueButtonPRO interface has a request from a patient or designated representative for their EHI from a past encounter with a provider at a given practice. The task is complete after an invite is processed, the 3<sup>rd</sup>-party app is validated, the patient/representative is authenticated, and their requested data have been received on the app. The data requested can range from partial to full EHI. Completing these task without assistance from Darena demonstrates ease of use and full interoperability.

Associated Criterion(a)	Measurement/Metric	Relied Upon Software(if applicable)	Outcomes	Challenges Encountered(if applicable)
<p>170.315(g)(7): Application Access – Patient Selection</p> <p>170.315(g)(10): Standardized API for Patient and Population Services (cures Update)</p>	<p>The patient/authorized representative will have the ability to access (after authentication) partial summary PHI by way of a FHIR-based API call from a 3<sup>rd</sup>-party application running on a patient-owned device through the API of the EHR</p>	<p>N/A</p>	<p>The BlueButtonPRO application performed with zero defects. All activity was conducted within a secure production environment and accessed their real patient data. The Real World Testing demonstrated that the clinician has the functionality within their EHR to receive a request with sufficient information to uniquely identify a patient and return an ID or other token that can be used by an application to subsequently execute requests for that patient’s data. The EHR demonstrated the functionality to respond to specific date range requests for patient data (single and bulk) containing partial data categories specified in the USCDI v1 Data Set and including full EHI This one-time return of such data (according to the specified standards, where applicable) allowed the patient/authorized representative to view and transmit the data, as needed, on their application on their selected device. The application responded to requests for patient data associated with a specific dates, as well as requests for patient data within a specified date range. A 0% error rate was observed.</p>	<p>There were no challenges encountered when testing and collecting data for these criteria.</p>

**KEY MILESTONES**

*Include a list of key milestones that were met during the Real World Testing process. Include details on how and when the developer implemented measures and collected data. Key milestones should be relevant and directly related to outcomes discussed.*

*For each key milestone, describe when Real World Testing began in specific care settings and the date/timeframe during which data was collected.*

Key Milestone	Care Setting	Date/Timeframe
Prepare the BlueButtonPRO for use for collection of EHI data upon requests by patients/authorized representatives.	Ambulatory Setting	December 2021
Identify the user practices the will participate in the test plan.	Ambulatory Setting Multiple Specialties	December 2021 & January 2022
Confirm that the Real World Test Plan participants are able to log into their accounts and are ready to demonstrate the request and response for patient EHI.	Ambulatory Setting Multiple Specialties	January 2022
Follow-up with the Real World Test Plan participants on a regular basis (minimum, once a quarter) to obtain feedback on their progress and or if there are any issues to address.	Ambulatory Setting Multiple Specialties	Quarterly 2022
End the Real World Test to coincide with the end of the 2022 calendar year.	Ambulatory Setting Multiple Specialties	January 2023
Real World Test analysis and generation of the report	Ambulatory Setting Multiple Specialties	January 2023
Submit Real World Test Report to ACB before established deadline	Ambulatory Setting Multiple Specialties	February 2023



**ATTESTATION**

The following is an attestation of the Darena Solutions LLC 2022 Real World Testing Results Report for BlueButtonPRO.

This Real World Testing Results Report is complete with all required elements, including measures that address all certification criteria and care settings. All information in this plan is up to date and fully addresses the Health IT Developer's Real World Testing requirements.

Authorized Representative Name: Wayne Singer

Authorized Representative Email: [wayne@darenasolutions.com](mailto:wayne@darenasolutions.com)

Authorized Representative Phone: 832-736-2552

Authorized Representative Signature: \_\_\_\_\_

A handwritten signature in black ink, appearing to read 'Wayne Singer', written over a horizontal line.

Date: 2/1/2023